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William F. DeGrado

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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/801,951
Filing Date: March 17, 2004
Appellant(s): DEGRADO ET AL.

Ms. Marsha A. Rose
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/23/09 appealing from the Office action mailed 2/2/09.

(1) *Real Party in Interest*

A statement identifying by name the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) *Summary of Claimed Subject Matter*

The summary of the claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) *Claims Appendix*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) *Evidence Relied Upon*

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent 7,173,102 B2

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-48, 67-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-8, 11, 14-15, 20-22, 26 of U.S. Patent No. 7,173,102 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced claims recite a method of killing microorganisms by contacting a surface with a compound of formula II, whereas the instant claims recite the same compound of formula II in a method of treating a microbial infection in an animal.

A preferred polymer or oligomer in the referenced claims is represented by a compound of formula I, where X can be NR₃, NHNH (where R₃ is hydrogen), O, S; Y

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can be CO; both A and B are independently optionally substituted o-, m-, p-phenylene, or optionally substituted heteroarylene wherein one of A and B is substituted with a polar (P) group and a nonpolar (NP) group and the other of A and B is substituted with neither a polar nor a nonpolar group; NP can be R₄, -U-(CH₂)_p-R₄, wherein R₄ can be hydrogen, C1-C2 alkyl, C3-C18 branched alkyl, P is a polar group selected from hydroxyethoxymethyl or -U-(CH₂)_p-V, where U is O or S and V can be amino, guanidine; p is 0 to 8; and m is 2 to at least 500; R₁ is (i) -y-C, (ii) H, or (iii) R₁ and R₂ together are a single bond; R₂ is -x-(CH₂)_p-W wherein W is H, V, N-maleimide, phenyl optionally substituted with up to three substituents selected from the group consisting of V, alkyl, carboxy, etc. Representative "heterocycles" include pyridine, cyclic guanidines, imidazole, piperidine, piperazine, etc. (claims 1, 4-8, 11, 14-15, 20-22, 26).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer to an animal infected with a microorganism a pharmaceutical composition comprising a compound of formula I or II as disclosed by the referenced claims.

A person of ordinary skill in the art would have been motivated to administer to an animal infected with a microorganism a pharmaceutical composition comprising an oligomer of formula I because: (1) of general teaching that the disclosed oligomers inhibit the growth of microorganisms on a surface; (2) interpreting the term "substrate" broadly includes any surface in need of killing microorganism, such as the skin or internal organs; and (3) animals with a microbial infection is a species within the broad genus of substrates. Therefore, one of ordinary skill in the art would have had a

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reasonable expectation of success in treating a microbial infection in an animal by administering a composition comprising an oligomer of formula I.

Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

(10) Response to Argument

Appellant argues nonobviousness because the instant claims are drawn to a method of treating a microbial infection in an animal, whereas the referenced claims are drawn to a method of killing microorganisms on a substrate, such as wood, cloth, or metal, both using the same oligomer as the active agent. Appellant argues that the term "substrate" is taken out of context and meant to encompass inanimate surfaces, not living tissues.

This is not persuasive because the obviousness rejection is over claims 1, 4-8, 11, 14-15, 20-22, 26 of U.S. Patent No. 7,173,102 B2, which recite the broad term "substrate," however do not specifically state the metes and bounds of the term. Therefore, the Examiner has looked to the specification for the full scope of the term "substrate" as it refers to the claimed invention.

The reference teaches that the scope of the term "substrates" broadly includes any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with the disclosed oligomers. In fact, testing of the bacterial efficacy has been performed in mammals with these polymers in water (col. 24, lines 57-64, example 5-6). DeGrado et al. teaches a need to design these polymers with reduced toxicity to

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birds, fish, mammals, and other higher organisms. Furthermore, any object that is exposed to or susceptible to bacterial or microbial contamination can be treated with these polymers, particularly in food and health care, for example for the use in contact lenses. Both pets and agronomic animals are exposed to and harbor a variety of infectious pathogenic organisms that can cause disease in animals or humans (col. 27, lines 1-28).

Therefore, it is clear that the Degrado et al. patent encompasses living tissue. Appellant is reminded that terms in the claims must be given its broadest reasonable interpretation that is consistent with the specification.

Appellant also argue that an oligomer that functions as an antimicrobial agent, when attached or applied to a surface, such as wood or cloth, would not necessarily be effective in treating a microbial infection in an animal when administered to the animal by parental injection of the pharmaceutical composition. Appellant argue that the previously submitted Nicolau and Bermudez Declarations state that "a person of ordinary skill in the art would not necessarily expect a polymer shown to function as an antimicrobial agent when attached to or incorporated into an object to be effective in treating a microbial infection in an animal" because of toxic and safety issues.

This is not persuasive because the Nicolau and Bermudez Declarations do not present any factual evidence toward nonobviousness, but rather is merely an opinion statement. The Declaration do not present any toxicity or safety reports of the claimed oligomers that are commensurate with the scope of the claims nor do they make a side by side comparison with the closest prior art. Appellant is reminded that the standard

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for obviousness is not absolute but a reasonable expectation of success. Since the claimed oligomers are known as antimicrobial agents, it is obvious to use it on living organisms infected with microorganisms with a reasonable expectation of success, especially since the term “substrate” encompasses living organisms as defined by the specification.

Appellant argues that the Examiner has not satisfied his burden of establishing that administering shorter oligomers to treat a microbial infection in an animal is prima facie obvious. Specifically, Degrado et al. teach the same polymer with 2 to about 500 monomer units, whereas the instant invention claims 1 to about 20 monomer units. There is no rational to select this particular subgenus. Appellant submit via the Bermudez Declaration that a person of ordinary skill in the art would not expect that an oligomer containing only 1 to about 20 monomer units to be applied to the surface of an object would necessarily be effective when administered to an animal to treat microbial infection.

This is not persuasive because at the outset, Degrado et al. teach the genus of monomer units that almost encompasses the claimed subgenus of monomer units. Therefore, absent unexpected results, the genus renders a species or subgenus, in this case, prima facie obvious. Further, Degrado et al. teach a narrower subgenus of 2 to about 30 monomer units in dependent claims such as claim 2. Therefore, there can be no valid argument made that 1 to about 20 monomer units are not obvious over a teaching of 2 to about 30 monomer units.

Furthermore, the Examiner also makes the point that in polymer science, one of ordinary skill in the art knows that when multiple repeat monomer units are present or as one increases the number of monomer units, the polymer behaves very similarly in terms of physical and chemical properties, no matter what the number of monomer units is. Therefore, at the very least, polymers with repeat units in the teens and twenties and beyond are obvious over one another.

With respect to the argument regarding the Bermudez Declaration, Examiner submits that the Declaration is merely an opinion, which is not supported by any factual evidence. Examiner reminds Appellant that the Degrado et al. reference is an issued US Patent. Therefore, a patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. *35 U.S.C. 282 Presumption of Validity*

(11) *Related Proceeding(s) Appendix*

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Yong S. Chong/

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